

PATENT COOPERATION TREATY
PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 05 SEP 2005

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Applicant's or agent's file reference 13739247	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/AU2004/001434	International filing date (day/month/year) 20 October 2004	Priority date (day/month/year) 20 October 2003
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ C12Q 1/68		
Applicant ST VINCENT'S HOSPITAL (SYDNEY) LIMITED et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☐ (sent to the applicant and to the International Bureau) a total of sheets, as follows:
 - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:
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|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

Date of submission of the demand 19 August 2005	Date of completion of the report 25 August 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer PHILIPPA WYRDEMAN Telephone No. (02) 6283 2554

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/001434

Box No. I	Basis of the report																														
1.	<p>With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.</p> <p><input type="checkbox"/> This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:</p> <p><input type="checkbox"/> international search (under Rules 12.3 and 23.1 (b))</p> <p><input type="checkbox"/> publication of the international application (under Rule 12.4)</p> <p><input type="checkbox"/> international preliminary examination (under Rules 55.2 and/or 55.3)</p>																														
2.	<p>With regard to the elements of the international application, this report is based on (<i>replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report</i>):</p> <p><input checked="" type="checkbox"/> the international application as originally filed/furnished</p> <p><input type="checkbox"/> the description:</p> <table border="0"> <tr> <td>pages</td> <td>as originally filed/furnished</td> <td></td> </tr> <tr> <td>pages*</td> <td>received by this Authority on</td> <td>with the letter of</td> </tr> <tr> <td>pages*</td> <td>received by this Authority on</td> <td>with the letter of</td> </tr> </table> <p><input type="checkbox"/> the claims:</p> <table border="0"> <tr> <td>pages</td> <td>as originally filed/furnished</td> <td></td> </tr> <tr> <td>pages*</td> <td>as amended (together with any statement) under Article 19</td> <td></td> </tr> <tr> <td>pages*</td> <td>received by this Authority on</td> <td>with the letter of</td> </tr> <tr> <td>pages*</td> <td>received by this Authority on</td> <td>with the letter of</td> </tr> </table> <p><input type="checkbox"/> the drawings:</p> <table border="0"> <tr> <td>pages</td> <td>as originally filed/furnished</td> <td></td> </tr> <tr> <td>pages*</td> <td>received by this Authority on</td> <td>with the letter of</td> </tr> <tr> <td>pages*</td> <td>received by this Authority on</td> <td>with the letter of</td> </tr> </table> <p><input type="checkbox"/> a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.</p>	pages	as originally filed/furnished		pages*	received by this Authority on	with the letter of	pages*	received by this Authority on	with the letter of	pages	as originally filed/furnished		pages*	as amended (together with any statement) under Article 19		pages*	received by this Authority on	with the letter of	pages*	received by this Authority on	with the letter of	pages	as originally filed/furnished		pages*	received by this Authority on	with the letter of	pages*	received by this Authority on	with the letter of
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3.	<p><input type="checkbox"/> The amendments have resulted in the cancellation of:</p> <p><input type="checkbox"/> the description, pages</p> <p><input type="checkbox"/> the claims, Nos.</p> <p><input type="checkbox"/> the drawings, sheets/figs</p> <p><input type="checkbox"/> the sequence listing (<i>specify</i>):</p> <p><input type="checkbox"/> any table(s) related to the sequence listing (<i>specify</i>):</p>																														
4.	<p><input type="checkbox"/> This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).</p> <p><input type="checkbox"/> the description, pages</p> <p><input type="checkbox"/> the claims, Nos.</p> <p><input type="checkbox"/> the drawings, sheets/figs</p> <p><input type="checkbox"/> the sequence listing (<i>specify</i>):</p> <p><input type="checkbox"/> any table(s) related to the sequence listing (<i>specify</i>):</p>																														

* If item 4 applies, some or all of those sheets may be marked "superseded."

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/001434**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-9	YES
	Claims	NO
Inventive step (IS)	Claims 1-9	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-9	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

- D1. HOLST, C. R. et al (April 2003), *Cancer Research* 63, 1596-1601.
D2. NAKAYAMA, H. et al (2002) *Cancer Letters*, 188, 115-119.

Novelty (N) and Inventive Step (IS)

D1 provides that *p16* methylated variant cells in histologically normal tissue may identify premalignant lesions before any morphological changes become apparent. In particular, cultures of human mammary epithelial cells from normal, cancer free women were examined from *p16* promoter hypermethylation

D2 provides assays based on the molecular detection of genetic changes in serum used as diagnostic tools for colorectal cancers. In particular, detection of methylation status (*p16* promoter methylation) in the serum of patients is used to detect early colorectal cancers

Both D1 and D2 are directed towards the identification of *p16* promoter methylation states as diagnostic tool for early detection of cancers as compared to a prognostic assay as required by the current claims. Further, neither of these citations isolate a population of cells from normal tissue nor the frequency of epimutation in a particular gene. Therefore, the claims are considered both novel and inventive.

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